CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number 21-260

ADMINISTRATIVE DOCUMENTS
CORRESPONDENCE

DEBARMENT STATEMENT

To whom it may concern

Elan Pharmaceutical Research Corporation hereby certifies that it did not and will not use in any capacity the services of any person debarred under Section 306 of the Federal Food, Drug and Cosmetic Act in connection with this application.

Signed

Roger Wayne Wiley, R.Ph.
Director Regulatory Affairs
Elan Pharmaceutical Research Corporation

APPEARS THIS WAY
ON ORIGINAL

FINANCIAL DISCLOSURE

Financial Disclosure Certifications are attached for each study. Individual Investigator Disclosure statements are stored at Elan Pharmaceutical Research Corporation and are available on request.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Food and Drug Administration

Form Approved: OMB No. 0910-0396
Expiration Date: 3/31/02

CERTIFICATION: FINANCIAL INTERESTS AND ARRANGEMENTS OF CLINICAL INVESTIGATORS

TO BE COMPLETED BY APPLICANT

With respect to all covered clinical studies (or specific clinical studies listed below (if appropriate)) submitted in support of this application, I certify to one of the statements below as appropriate. I understand that this certification is made in compliance with 21 CFR part 54 and that for the purposes of this statement, a clinical investigator includes the spouse and each dependent child of the investigator as defined in 21 CFR 54.2(d).

Please mark the applicable checkbox.

(1) As the sponsor of the submitted studies, I certify that I have not entered into any financial arrangement with the listed clinical investigators (enter names of clinical investigators below or attach list of names to this form) whereby the value of compensation to the investigator could be affected by the outcome of the study as defined in 21 CFR 54.2(a). I also certify that each listed clinical investigator required to disclose to the sponsor whether the investigator had a proprietary interest in this product or a significant equity in the sponsor as defined in 21 CFR 54.2(b) did not disclose any such interests. I further certify that no listed investigator was the recipient of significant payments of other sorts as defined in 21 CFR 54.2(f).

Clinical Investigators		
	See attached investigator list for	
	Protocol TRG004-01	

(2) As the applicant who is submitting a study or studies sponsored by a firm or party other than the applicant, I certify that based on information obtained from the sponsor or from participating clinical investigators, the listed clinical investigators (attach list of names to this form) did not participate in any financial arrangement with the sponsor of a covered study whereby the value of compensation to the investigator for conducting the study could be affected by the outcome of the study (as defined in 21 CFR 54.2(a)); had no proprietary interest in this product or significant equity interest in the sponsor of the covered study (as defined in 21 CFR 54.2(b)); and was not the recipient of significant payments of other sorts (as defined in 21 CFR 54.2(f)).

(3) As the applicant who is submitting a study or studies sponsored by a firm or party other than the applicant, I certify that I have acted with due diligence to obtain from the listed clinical investigators (attach list of names) or from the sponsor the information required under 54.4 and it was not possible to do so. The reason why this information could not be obtained is attached.

NAME	TITLE
Pia Mikkelsen Lynch, M.D.	Director, Clinical Research
FIRM/ORGANIZATION: Elan Pharmaceutical Research Corporation	
SIGNATURE: Pia Mikkelsen Lynch	DATE: 5/12/00

Paperwork Reduction Act Statement

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Public reporting burden for this collection of information is estimated to average 1 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the necessary data, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information to the address to the right:

Department of Health and Human Services
Food and Drug Administration
5600 Fishers Lane, Room 14C-03
Rockville, MD 20857

000030

Appendix to Federal FDA 3454:
Certification: Financial Interests and Arrangements of Clinical Investigators

Protocol: TRG004-01 An Open Steady-State Pharmacokinetics Study of _____™ (morphine sulfate oral extended release capsules) in Patients with Chronic, Moderate to Severe Pain.

List of Investigators Certified under statement number 1:

[redacted]

APPEARS THIS WAY
ON ORIGINAL

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
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CERTIFICATION: FINANCIAL INTERESTS AND ARRANGEMENTS OF CLINICAL INVESTIGATORS

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Clinical Investigators		
	See attached investigator list for	
	Protocol TRG004-02	

(2) As the applicant who is submitting a study or studies sponsored by a firm or party other than the applicant, I certify that based on information obtained from the sponsor or from participating clinical investigators, the listed clinical investigators (attach list of names to this form) did not participate in any financial arrangement with the sponsor of a covered study whereby the value of compensation to the investigator for conducting the study could be affected by the outcome of the study (as defined in 21 CFR 54.2(a)); had no proprietary interest in this product or significant equity interest in the sponsor of the covered study (as defined in 21 CFR 54.2(b)); and was not the recipient of significant payments of other sorts (as defined in 21 CFR 54.2(f)).

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SIGNATURE: Pia Mikkelsen Lynch	DATE: 5/12/00

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5600 Fishers Lane, Room 14C-03
Rockville, MD 20857

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FORM FDA 3454 (3/99)

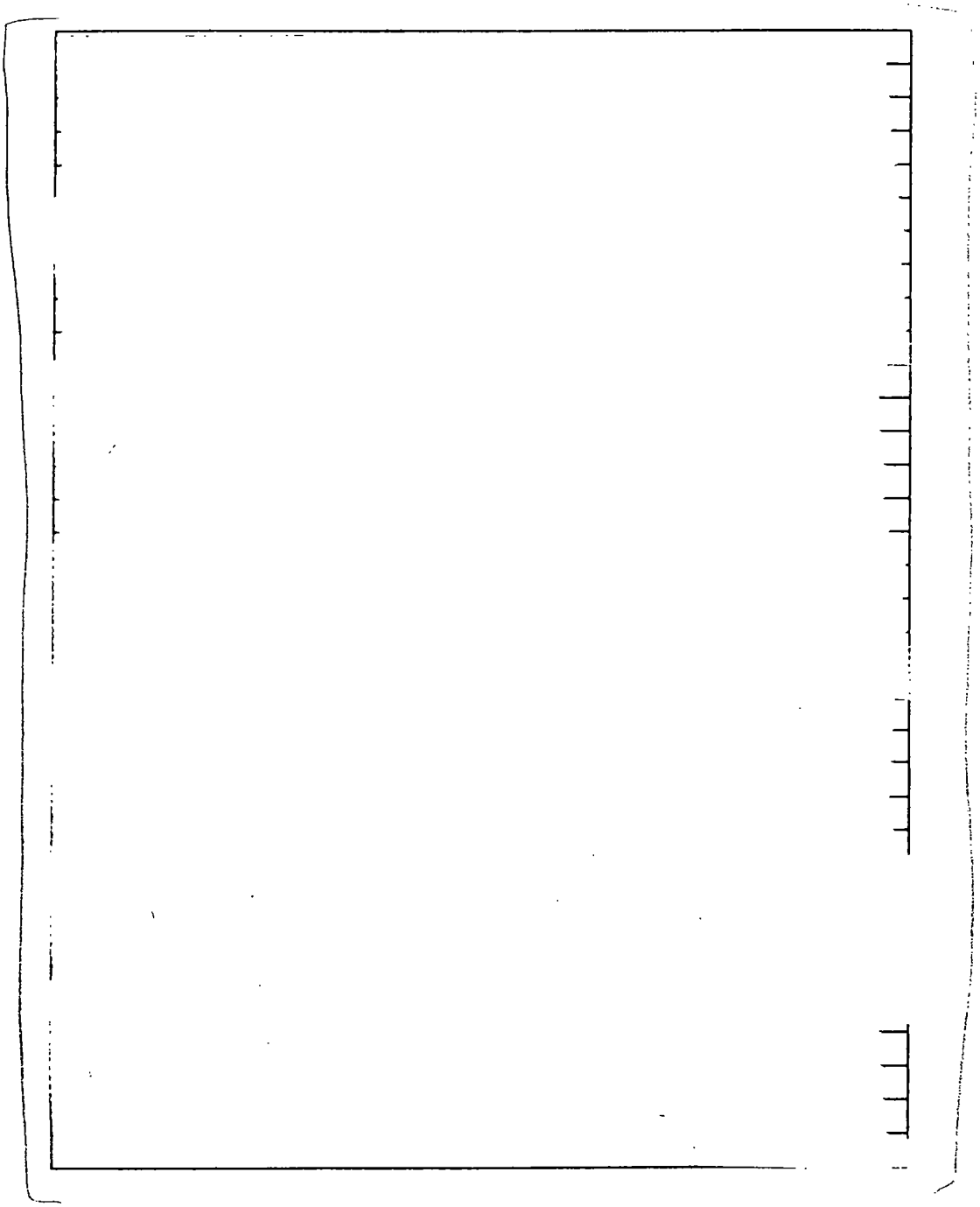
Created by Electronic Document Services/USDHHS (301) 443-2454 EF

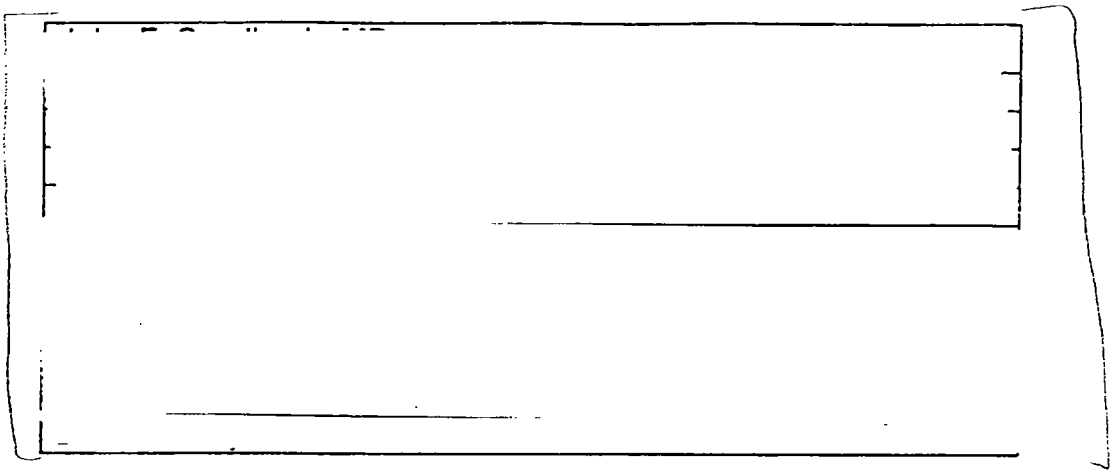
Elan Pharmaceutical Research Corporation
TRG004-02; Form 3454

Appendix to Federal FDA 3454:
Certification: Financial Interests and Arrangements of Clinical Investigators

Protocol: TRG004-02 – A Multicenter, Randomized, Double-Blind, Double – Dummy Parallel Groups Study of Morphelan (Morphine Sulfate Oral Extended Release Capsules) in Patients with Chronic, Moderate to Severe Pain.

List of Investigators Certified under statement number 1:





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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Food and Drug Administration

Form Approved: OMB No. 0910-0396
Expiration Date: 3/31/02

CERTIFICATION: FINANCIAL INTERESTS AND ARRANGEMENTS OF CLINICAL INVESTIGATORS

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With respect to all covered clinical studies (or specific clinical studies listed below (if appropriate)) submitted in support of this application, I certify to one of the statements below as appropriate. I understand that this certification is made in compliance with 21 CFR part 54 and that for the purposes of this statement, a clinical investigator includes the spouse and each dependent child of the investigator as defined in 21 CFR 54.2(d).

Please mark the applicable checkbox.

(1) As the sponsor of the submitted studies, I certify that I have not entered into any financial arrangement with the listed clinical investigators (enter names of clinical investigators below or attach list of names to this form) whereby the value of compensation to the investigator could be affected by the outcome of the study as defined in 21 CFR 54.2(a). I also certify that each listed clinical investigator required to disclose to the sponsor whether the investigator had a proprietary interest in this product or a significant equity in the sponsor as defined in 21 CFR 54.2(b) did not disclose any such interests. I further certify that no listed investigator was the recipient of significant payments of other sorts as defined in 21 CFR 54.2(f).

Clinical Investigators		
	See attached investigator list for	
	Protocol TRG004-03	

(2) As the applicant who is submitting a study or studies sponsored by a firm or party other than the applicant, I certify that based on information obtained from the sponsor or from participating clinical investigators, the listed clinical investigators (attach list of names to this form) did not participate in any financial arrangement with the sponsor of a covered study whereby the value of compensation to the investigator for conducting the study could be affected by the outcome of the study (as defined in 21 CFR 54.2(a)); had no proprietary interest in this product or significant equity interest in the sponsor of the covered study (as defined in 21 CFR 54.2(b)); and was not the recipient of significant payments of other sorts (as defined in 21 CFR 54.2(f)).

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Pia Mikkelsen Lynch, M.D.	Director, Clinical Research
FIRM/ORGANIZATION: Elan Pharmaceutical Research Corporation	
SIGNATURE: Pia Mikkelsen Lynch	DATE: 5/12/00

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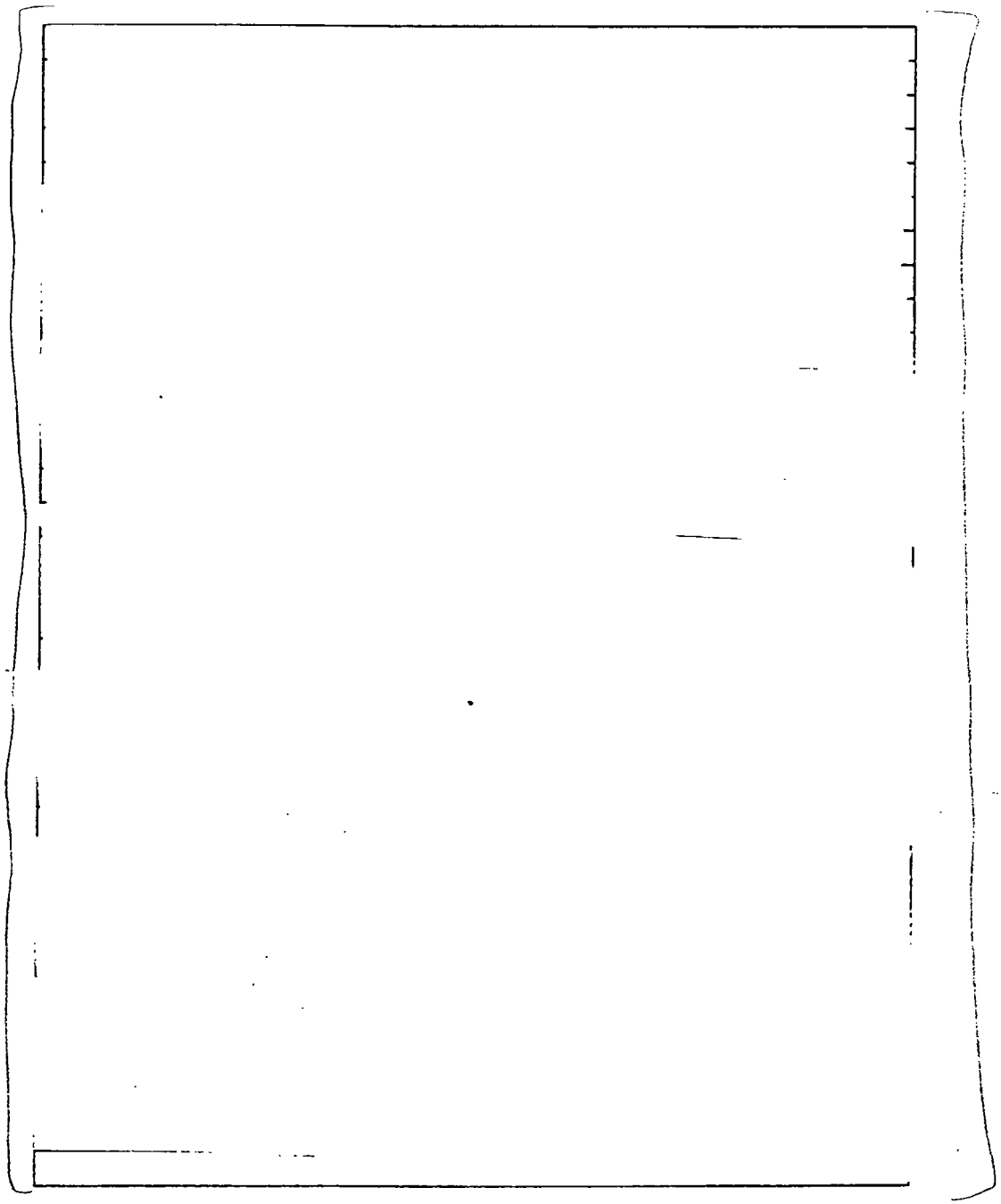
Food and Drug Administration
5600 Fishers Lane, Room 14C-03
Rockville, MD 20857

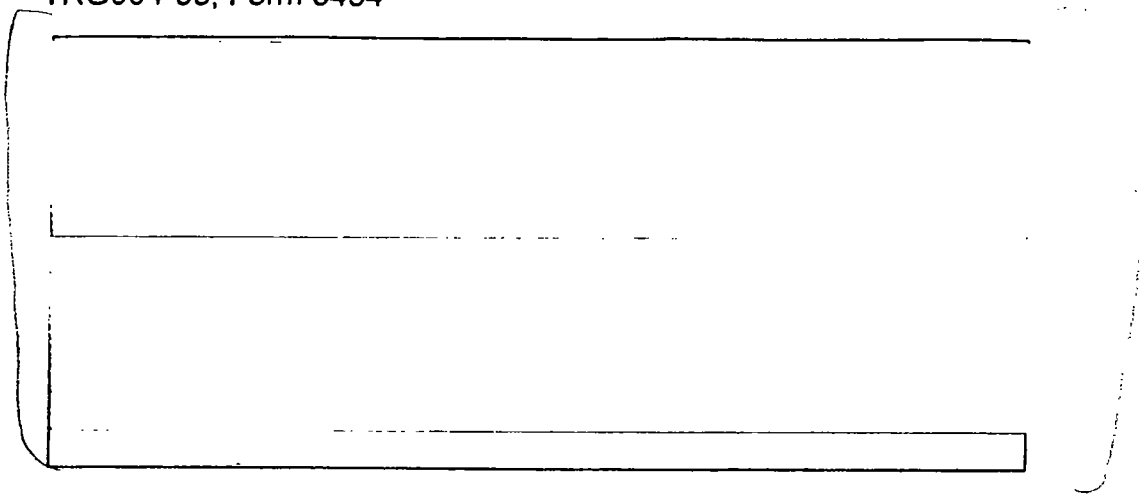
000035

Appendix to Federal FDA 3454:
Certification: Financial Interests and Arrangements of Clinical Investigators

Protocol: TRG004-03 – A Multicenter, Non-Randomized, Open-Extension Study of Morphelan™ (morphine sulfate oral extended release capsules) in Patients with Chronic, Moderate to Severe Pain Who Have Completed A Prior Morphelan Clinical Trial.

List of Investigators Certified under statement number 1:





DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Food and Drug Administration

Form Approved: OMB No. 0910-0396
Expiration Date: 3/31/02

CERTIFICATION: FINANCIAL INTERESTS AND ARRANGEMENTS OF CLINICAL INVESTIGATORS

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Clinical Investigators		
	See attached investigator list for	
	Protocol TRG004-04 Double-Blind	

(2) As the applicant who is submitting a study or studies sponsored by a firm or party other than the applicant, I certify that based on information obtained from the sponsor or from participating clinical investigators, the listed clinical investigators (attach list of names to this form) did not participate in any financial arrangement with the sponsor of a covered study whereby the value of compensation to the investigator for conducting the study could be affected by the outcome of the study (as defined in 21 CFR 54.2(a)); had no proprietary interest in this product or significant equity interest in the sponsor of the covered study (as defined in 21 CFR 54.2(b)); and was not the recipient of significant payments of other sorts (as defined in 21 CFR 54.2(f)).

(3) As the applicant who is submitting a study or studies sponsored by a firm or party other than the applicant, I certify that I have acted with due diligence to obtain from the listed clinical investigators (attach list of names) or from the sponsor the information required under 54.4 and it was not possible to do so. The reason why this information could not be obtained is attached.

NAME	TITLE
Pia Mikkelsen Lynch, M.D.	Director, Clinical Research
FIRM/ORGANIZATION	
Elan Pharmaceutical Research Corporation	
SIGNATURE	**DATE**
Pia Mikkelsen Lynch	5/12/00

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Department of Health and Human Services
Food and Drug Administration
5600 Fishers Lane, Room 14C-03
Rockville, MD 20857

000038

Elan Pharmaceutical Research Corporation
TRG004-04 Double Blind

Appendix to Federal FDA 3454:
Certification: Financial Interests and Arrangements of Clinical Investigators

Protocol: TRG004-04 – A Double-Blind, Placebo Controlled, Parallel Group Comparison of the Efficacy and Safety of Morphelan, MS Contin, and Placebo with an Open Label Extension in the Treatment of Osteoarthritis of the Knee and/or Hip.

List of Investigators Certified under statement number 1:

[redacted]

APPEARS THIS WAY
ON ORIGINAL

000039

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Food and Drug Administration

CERTIFICATION: FINANCIAL INTERESTS AND ARRANGEMENTS OF CLINICAL INVESTIGATORS

Form Approved: OMB No. 0910-0396
Expiration Date: 3/31/02

TO BE COMPLETED BY APPLICANT

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Please mark the applicable checkbox.

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Clinical Investigators		
	See attached investigator list for	
	Protocol TRG004-04 Open Label Extension	

(2) As the applicant who is submitting a study or studies sponsored by a firm or party other than the applicant, I certify that based on information obtained from the sponsor or from participating clinical investigators, the listed clinical investigators (attach list of names to this form) did not participate in any financial arrangement with the sponsor of a covered study whereby the value of compensation to the investigator for conducting the study could be affected by the outcome of the study (as defined in 21 CFR 54.2(a)); had no proprietary interest in this product or significant equity interest in the sponsor of the covered study (as defined in 21 CFR 54.2(b)); and was not the recipient of significant payments of other sorts (as defined in 21 CFR 54.2(f)).

(3) As the applicant who is submitting a study or studies sponsored by a firm or party other than the applicant, I certify that I have acted with due diligence to obtain from the listed clinical investigators (attach list of names) or from the sponsor the information required under 54.4 and it was not possible to do so. The reason why this information could not be obtained is attached.

NAME	TITLE
Pia Mikkelsen Lynch, M.D.	Director, Clinical Research
FIRM/ORGANIZATION: Elan Pharmaceutical Research Corporation	
SIGNATURE: Pia Mikkelsen Lynch	DATE: 5/12/00

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Department of Health and Human Services
Food and Drug Administration
5600 Fishers Lane, Room 14C-03
Rockville, MD 20857

000040

Appendix to Federal FDA 3454:
Certification: Financial Interests and Arrangements of Clinical Investigators

Protocol: Open Label Extension Portion of TRG004-04 - A Double-Blind, Placebo Controlled, Parallel Group Comparison of the Efficacy and Safety of Morphelan, MS Contin, and Placebo with an Open Label Extension in the Treatment of Osteoarthritis of the Knee and/or Hip.

List of Investigators Certified under statement number 1:

[redacted]

APPEARS THIS WAY
ON ORIGINAL

000041

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Food and Drug Administration

Form Approved: OMB No. 0910-0396
Expiration Date: 3/31/02

CERTIFICATION: FINANCIAL INTERESTS AND ARRANGEMENTS OF CLINICAL INVESTIGATORS

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Clinical Investigators		
	See attached investigator list for	
	Protocol TRG004-05	

(2) As the applicant who is submitting a study or studies sponsored by a firm or party other than the applicant, I certify that based on information obtained from the sponsor or from participating clinical investigators, the listed clinical investigators (attach list of names to this form) did not participate in any financial arrangement with the sponsor of a covered study whereby the value of compensation to the investigator for conducting the study could be affected by the outcome of the study (as defined in 21 CFR 54.2(a)); had no proprietary interest in this product or significant equity interest in the sponsor of the covered study (as defined in 21 CFR 54.2(b)); and was not the recipient of significant payments of other sorts (as defined in 21 CFR 54.2(f)).

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FIRM/ORGANIZATION: Elan Pharmaceutical Research Corporation	
SIGNATURE: Pia Mikkelsen Lynch	DATE: 5/12/00

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Rockville, MD 20857

000042

Appendix to Federal FDA 3454:
Certification: Financial Interests and Arrangements of Clinical Investigators

Protocol: TRG004- A Multicenter, Randomized, Incomplete Block, Double-Blind, Double-Dummy, 2-Period Crossover Study Comparing the Pharmacokinetics and Pharmacodynamics of Once-Daily Morphelan™ (morphine sulfate oral sustained release capsules) and Twice Daily MST Continus in Patients with Chronic, Moderate to Severe Pain of Malignant or Non-malignant Origin.

List of Investigators Certified under statement number 1:

[redacted]

DEPARTMENT OF HEALTH AND HUMAN SERVICES
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Food and Drug Administration

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Clinical Investigators		
	See attached investigator list for	
	Protocol TRG004-06	

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Pia Mikkelsen Lynch, M.D.	Director, Clinical Research
FIRM/ORGANIZATION: Elan Pharmaceutical Research Corporation	
SIGNATURE: Pia Mikkelsen Lynch	DATE: 5/12/00

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Rockville, MD 20857

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FORM FDA 3454 (3/99)

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Appendix to Federal FDA 3454:
Certification: Financial Interests and Arrangements of Clinical Investigators

Protocol: TRG004-06 – A Multicenter, Randomized, Incomplete Block, Double-Blind, Double-Dummy, 2-Period Crossover Study Comparing the Pharmacokinetic-Pharmacodynamic Relationships of Once-Daily Morphelan™ (morphine sulfate oral sustained release capsules) and Twice Daily MS Contin® in Patients with Chronic, Moderate to Severe Pain of Non-Malignant Origin

List of Investigators Certified under statement number 1: